



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/593,800

03/08/2007

Douglas H. Robinson

13355/10901

4462

23838 7590 09/22/2010

KENYON & KENYON LLP
1500 K STREET N.W.
SUITE 700
WASHINGTON, DC 20005

EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

09/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,800	Applicant(s) ROBINSON, DOUGLAS H.	
	Examiner Mark Navarro	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-38 is/are pending in the application.
- 4a) Of the above claim(s) 7-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment filed August 17, 2010 has been received and entered. Claim 2 has been cancelled. Accordingly, claims 1 and 3-38 are pending in the instant application, of which claims 7-38 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. The rejection of claims 1 and 3-6 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is maintained.

Applicants are asserting that “cells found in nature do not have the characteristics of the culture of morphotes of claims 1 and 3-6,” and that the culture of morphotes of claims 1 and 3-6 are not any products of nature, and that in contrast the culture of morphotes of claims 1 and 3-6 are made by humans.

Applicants arguments have been fully considered but are not found to be persuasive.

Applicants assert that “cells found in nature do not have the characteristics of the culture of morphotes of claims 1 and 3-6.” However, Applicants are respectfully directed back to their own claim language, which recites: “A culture of morphotes obtained from mammalian tissues, wherein...”. The claim encompasses morphotes directly obtained from mammalian tissue, there is no claim limitation of treating the

morphotes with some chemical not found naturally in nature, there is no process of subjecting the cells to some procedure not found in nature (e.g., centrifugation). The claims encompass morphotes obtained from mammalian tissues without elaborating within the claim how that is done. Accordingly, the claim language currently allows for obtaining morphotes directly from a mammalian tissue, mammalian tissue being a product of nature.

Claims 1 and 3-6 are directed to cultures comprising morphotes which have the same characteristics and utility as morphotes found naturally and therefore does not constitute as patentable subject matter.

In the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 US 566 (1974); American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Inoculant Co. 33 US 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment to the claims to recite the essential purity of the claimed products is suggested to obviate this rejection. For example, "An isolated culture of morphotes ..."

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1 and 3-6 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is maintained.

Applicants are asserting that the specification discloses that the morphote cultures of the invention exhibit distinguishing attributes shared by the members of the genus: resembling prokaryotic cells at the unicellular level with the ability to self-organize in vitro into multicellular, mammalian eukaryotic tissue-like patterns, wherein the patterns can be tissue-like sheets, capillary-like networks and trabecular bone-like structures. Applicants further assert that Example 17 in the Guidelines for the Examination of Patent Applications under 35 USC 112, first paragraph's written description are directed to methods, while the pending claims 1 and 3-6 are directed to a product, a culture of morphotes, and consequently, Example 17 is not germane.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the specification discloses that the morphote cultures of the invention exhibit distinguishing attributes shared by the members of the genus: resembling prokaryotic cells at the unicellular level with the ability to self-organize in vitro into multicellular, mammalian eukaryotic tissue-like patterns, wherein the patterns can be tissue-like sheets, capillary-like networks and trabecular bone-like structures.

Art Unit: 1645

However, Applicants have recited several properties that the morphote cultures share when cultured in vitro, the claims have no structural requirement (e.g., each morphote cell comprising SEQ ID NO: X, etc).

Second, Applicants assert that Example 17 in the Guidelines for the Examination of Patent Applications under 35 USC 112, first paragraph's written description are directed to methods, while the pending claims 1 and 3-6 are directed to a product, a culture of morphotes, and consequently, Example 17 is not germane. However, Applicants are specifically directed to Example 17, claim 3, which recites "A compound identified by the method of claim 2." This is directly analogous to the instantly claimed product, culture of morphotes in claim 1. Applicants specification (Example 1) sets forth of a method of treating mammalian tissue with alternating anaerobic and aerobic atmospheres to produce a culture of morphotes. Based on this method of producing Applicants have claimed the final product produced via this method, as explained in Example 17 of the written description guidelines, this does not satisfy the written description requirement for the product. The specification describes a method of alternating anaerobic and aerobic conditions to produce a morphote, however there is no information regarding what structural features would likely be associated with such selective ability to exhibit tissue level multicellular self organization, etc. Thus, the specification does not disclose a correlation between selective ability to exhibit tissue level multicellular self organization and the structure of a morphote.

Claims 1 and 3-6 recite a culture of morphotes obtained from mammalian

Art Unit: 1645

tissues, wherein the morphotes exhibit tissue level multicellular self-organization into a multicellular, mammalian tissue like pattern when cultured in vitro. Applicants define morphotes as pleomorphic organisms which exhibit morphologic and genetic characteristics of both prokaryotic and eukaryotic cells. (Specification, page 1).

Applicants further describe a method for isolating morphotes by collecting lymphoma specimens and placing them in a culture medium under anaerobic conditions, followed by aerobic conditions, and followed yet again by anaerobic conditions. (Specification, Example 1).

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, “culture of morphotes/obtained by the described method of Example 1” alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.”

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Applicants are directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement, the guidelines can be found at the following link on the USPTO Internet in “Patents Guidance” Specifically, Example 17, which is analogous to the recitation of a claimed product (morphotes) identified via a method of production (description provided in Example 1).

<http://www.uspto.gov/web/patents/guides.htm>

For reasons of record as well as the reasons set forth above, this rejection is maintained.

3. The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the use of the phrase “derived” is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 1 and 3-6 under 35 U.S.C. 102(b) as being anticipated by Wainwright et al is maintained.

Applicants are asserting that the Examiner was incorrect in characterizing the organism isolated by Wainwright as having characteristics of eukaryotic cells.

Applicants further assert that the organism isolated by Wainwright does not exhibit tissue level multicellular self organization into a multicellular mammalian tissue like pattern, does not exhibit sheet like tissue level multicellular self organization when cultured in vitro, does not exhibit capillary like tissue level multicellular self organization when cultured in vitro, does not exhibit trabecular bone-like tissue level multicellular self organization when cultured in vitro, or three or more of the organism isolated by Wainwright do not connect or interconnect into networks of varying densities, scales, or dimensions that tessellate triangular, quadrilateral, and polygonal areas or shapes that contain no morphote cells.

Applicants arguments have been fully considered but are not found to be persuasive.

First, Applicants assert that the Examiner was incorrect in characterizing the organism isolated by Wainwright as having characteristics of eukaryotic cells. However, Applicants are again directed to the teaching of Wainwright et al, page 290, the culture turned pink-purple and "branched forms grew, and that under low magnification superficially appeared fungal." The appearance of being fungal is a eukaryotic morphological characteristic. Applicants defined the term "morphotes" as "pleomorphic organisms which exhibit morphologic and genetic characteristics of both prokaryotic and eukaryotic cells." (Specification page 1). Applicants do not further limit what morphologic or genetic characteristics are necessary. Accordingly, under the broadest reasonable interpretation standard, the "appeared fungal" observation is sufficient to meet the limitation of "morphologic characteristic of a eukaryote."

Applicants finally assert that the organism isolated by Wainwright does not exhibit tissue level multicellular self organization into a multicellular mammalian tissue like pattern, does not exhibit sheet like tissue level multicellular self organization when cultured in vitro, does not exhibit capillary like tissue level multicellular self organization when cultured in vitro, does not exhibit trabecular bone-like tissue level multicellular self organization when cultured in vitro, or three or more of the organism isolated by Wainwright do not connect or interconnect into networks of varying densities, scales, or dimensions that tessellate triangular, quadrilateral, and polygonal areas or shapes that contain no morphote cells. However, Applicants are arguing an intended use of the claimed morphote (e.g., cultured in vitro). The intended use phrase is not afforded any patentable weight. Furthermore, as set forth above, Wainwright discloses of a

Art Unit: 1645

composition of “morphotes” having pleomorphic properties of both prokaryotes and eukaryotes. Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, (morphote comprising pleomorphic properties of both prokaryotes and eukaryotes) the properties applicant discloses and/or claims (tissue level multicellular self organization) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The claims are directed to a culture of morphotes obtained from mammalian tissues, wherein the morphotes exhibit tissue-level multicellular self-organization into a multicellular, mammalian tissue like pattern when cultured in vitro.

Wainwright et al (Medical Hypotheses Vol. 60, No. 2, pp 290-292, Feb 2003/IDS REF 3) disclose of isolating highly pleomorphic bacterium having a number of morphological characteristics in common with many historical cancer germs. (See page 290). Wainwright et al further disclose that the culture turned pink-purple and “branched forms” grew, and that under low magnification superficially appeared fungal. (See page 290).

Given that Applicants have defined the term “morphotes” as pleomorphic organisms which exhibit morphologic and genetic characteristics of both prokaryotic and eukaryotic cells; and that Wainwright has isolated a culture of pleomorphic bacterium organisms (prokaryotic) from mammalian tissue, which superficially appeared fungal (eukaryotic), the disclosure of Wainwright et al is deemed to anticipate the instantly filed

Art Unit: 1645

claims.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

5. The rejection of claims 1 and 3-6 under 35 U.S.C. 102(b) as being anticipated by Robinson is maintained.

Applicants arguments are commensurate in scope with the arguments set forth above in rejection number 4, and have been fully addressed above in rejection number 4.

The claims are directed to a culture of morphotes obtained from mammalian tissues, wherein the morphotes exhibit tissue level multicellular self-organization into a multicellular, mammalian tissue like pattern when cultured in vitro.

Robinson et al (IDS REF 6; 2001) disclose of isolating prokaryotes from a sterile cell culture system in which sterile human eukaryotes were subjected to an oxygen environment of alternating anaerobiosis and aerobiosis. Robinson disclose that all prokaryotes isolated were classified as Gram-positive, and were often highly pleomorphic in culture. (See page 1). Robinson et al further report that immunoblot studies indicated that various prokaryotes so isolated expressed both human genes/proteins. (See again page 1).

Given that Applicants have defined the term “morphotes” as pleomorphic organisms which exhibit morphologic and genetic characteristics of both prokaryotic and

Art Unit: 1645

eukaryotic cells; and that Robinson isolated a culture of pleomorphic bacterium organisms (prokaryotic) from mammalian tissue, which also expressed both human genes/proteins (eukaryotic), the disclosure of Robinson is deemed to anticipate the instantly filed claims.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
September 20, 2010